

Serial No. 09/997,023
Docket No.: 010793-034000

REMARKS

The Examiner's final Office Action dated July 1, 2004 has been received and carefully considered. Applicant acknowledges with appreciation the Examiner's indication that claims 4, 9 and 11 contain subject matter that would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim. Claims 1-25, 46-52 and 64-67 are pending in the application. Claims 1-25, 46-52 and 64-67 have been rejected.

I. Claim Rejection Under 35 U.S.C. 102(b) in view of U.S. Patent No. 5,260,222 to Patel et al.

Claims 1-2, 5-7, 10, 12-13 and 64-67 are rejected under 35 U.S.C. 102(b) as being anticipated by the disclosure of U.S. Patent No. 5,260,222 to Patel et al. (hereinafter "Patel") For the reasons discussed below, Applicant respectfully disagrees.

First, with respect to Patel, it is argued in the Office Action that:

Patel *et al.* teaches a device (10) that has ports (12) that permit fluid to the bottom of the device. There is a first piece of bibulous material (32), and a second piece of bibulous material (34) and a piece of liquid expandable material (22). When material (28) expands, materials (32) and (34) are in fluid contact with one another. Material (28) expands as a result of fluid through port mark (20). Material (28) has been read on the claimed "expandable collection device." Material (34) can act as a reagent for analysis of a reagent.

See, Office Action, page 2.

Referring to Figures 2A, 2B, 3A, and 3B of Patel, the Examiner further takes the position that the housing (11), compressible member (24) and expandable member (22) of Patel reads on Applicant's claimed "holding portion," "retaining portion," and "expandable collector member," respectively.

Applicant submits, however, that Patel does not teach each and every limitation of the rejected claims. In particular, under the Examiner's interpretation of Patel, Patel does not teach the limitation of claim 1, "wherein a sufficient sample is collected for assay when the collector member second collection size is substantially equal to the retaining portion extended size." Rather, in the teachings of Patel, the expandable member (22) presses inward against compressible member (24) when a sample is collected, causing compressible member (22) to contract. Thus, the compressible member (24) which has been read on the claimed

Serial No. 09/997,023
Docket No.: 030793-034000

"retaining portion" clearly does not have a correlating "extended size" where a sample is collected by expandable member (22). Accordingly, Patel does not teach or suggest the invention of claim 1, "wherein a sufficient sample is collected for assay when the collector member second collection size is substantially equal to the retaining portion extended size." Therefore, since each and every aspect of claim 1 is not taught by Patel, Patel is not an anticipating reference 35 U.S.C. 102(b) as the Examiner suggests. *See e.g., Verchall Bros. v. Union Oil Co. of California*, 2 USP2d 1051, 1053 (Fed. Cir. 1987) ("a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."); *See also, Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) ("The identical invention must be shown in as complete detail as is contained in the . . . claim"). Applicant submits, therefore, that the rejection of claim 1 should be reconsidered and withdrawn. Inasmuch as rejected claims 2, 5-7, 10 and 12-13 are deemed to include each and every limitation of claim 1 by virtue of their depending from claim 1, the Examiner's rejection of these claims should also be withdrawn.

With respect to claim 2, 5-7, 10, 12-13, and 64-67, Applicant specifically notes that the Examiner's Office Action is silent with respect to the additional limitations of these claims. Applicant is, therefore, left without guidance as what features of Patel the Examiner believes reads on their limitations. Nevertheless, Applicant submits that Patel fails to teach each and every limitation of these claims. First with respect to claim 2, Applicant submits that the compressible member (24) which the Examiner alleges to read on the recited "retaining portion" does not include a corresponding "blocking portion defining a sample retaining size of the retaining portion which prevents movement of the retaining portion size to a size less than the sample retaining size being formed when the blocking portion engages with the holding portion second end," as recited in claim 2. Accordingly, Applicant submits that, for this reason also, the Examiner's rejection of claim 2 should be reconsidered and withdrawn.

Claim 6 is dependent on claim 2, and further includes the limitation of "wherein the retaining portion includes an elongate member, the blocking portion includes a raised portion formed on the elongate member, and the holding portion second end includes a wall sized to engage the raised portion when the retaining portion is moved from one of the extended size and the contracted size to the sample retaining size." The preferred embodiment on which these claims read are shown in Figures 3 of the application. Applicant submits that Patel does not teach or suggest this limitation of claim 6 and that the rejection of this claim should accordingly be reconsidered and withdrawn.

Serial No.: 09/997,023
Docket No.: 030793-034000

Claim 7 is dependent on claim 1, and includes the limitation, "wherein the holding portion includes a housing defining an opening for slidably receiving the retaining portion so as to permit the retaining portion to be selectively movable between at least one of the extended size and the contracted size." Applicant submits that the housing (11) of Patel that the Examiner contends reads on the recited "holding portion" does not define an opening for slidably receiving the expandable member (24) that the Examiner contends reads on the recited "retaining portion." Rather, in the device of Patel, arm (26) to which compressible member (24) is attached is fixed within device (10) so that compressible member (24) will not move within the device (10). See Patel, Col. 8, lines 60-65. It is clear, therefore, that Patel does not teach the limitation of claim 7. Accordingly, the rejection of claim 7 should be reconsidered and withdrawn.

Claim 10 is dependent on claim 1, and includes the limitation, "wherein the retaining portion includes a wall spaced at a first length from the holding portion second and when the retaining portion is in the expanded size and the wall is spaced at a second length from the holding portion when the retaining portion is in the contracted size." Applicant respectfully submits that the compressible member (24) of Patel which is said to read on the "retaining portion" does not include a "wall" as recited in claim 10. Accordingly, the Examiner's rejection of claim 10 should be reconsidered and withdrawn.

Claim 64 is directed to a method for collecting a sample adequate for assay comprising, *inter alia*, the steps of "providing a collector holder, the collector holder including a sample area for indicating whether the sample collector has collected a sample sufficient for assay, and disposing the sample collector within the sample area such that the entirety of the sample collector is contained within the sample area..." Again, the Examiner has not provided Applicant with any guidance as to what features of Patel are deemed to read on the steps recited in claim 64. Nevertheless, Applicant submits that Patel clearly does not disclose a collector holder having the recited "sample area." It follows, therefore, that Patel does not teach or suggest a method for collecting a sample adequate for assay comprising the step of "disposing the sample collector within the sample area..." as recited in claim 64. Accordingly, the Examiner's rejection of claim 64 should be reconsidered and withdrawn. Notwithstanding the fact that each of claims 65-67 are dependent on claim 64, and as such are deemed to include each and every element of claim 64, Applicant submits that Patel et al. also fail to teach those elements specifically recited in these dependent claims. Accordingly, these claims are also not anticipated, or otherwise rendered obvious, by Patel et al.

Serial No. 09/997,023
Docket No.: 0:0793-034000

**II. Claim Rejection Under 35 U.S.C. 102(b) in view of
U.S. Patent No. 5,198,193 to Bunce et al.**

Claims 1-2, 5-7, 10, 12-13 and 64-67 are also rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,198,193 to Bunce et al. (hereinafter "Bunce"). In particular, it is contended that Bunce et al. teach many different configurations that read on the instant claims. Figure 4, in particular, is noted as being exemplary. According to the Office Action, Figure 4 teaches a liquid transfer device comprising holding portion (70d) having a first and second ends, a retaining portion (32) attached to the holding portion, and expandable collection member (23d) having a first and second size and reagents (32d) to detect the analyte of interest. It is further contended in the disclosure of Bunce holding portion (70d) reads on the "holding" portion of the claimed "holding portion," retaining portion (32) reads on the claimed "retaining portion," and expandable member (23d) reads on the claimed "expandable collector member." Applicant respectfully disagrees.

First, Applicant notes that item (32) shown in Figure 4 of Bunce et al. is not a retaining portion as the Examiner suggest, but is a "serum separation layer" disposed on zone (31a), which acts as an analysis site where specific antibodies are immobilized in accordance with the method of Bunce. See Bunce, Col. 3, line 48-52. Moreover, even if the serum separation layer (32) could be read on the "retaining portion" of claim 1, the serum separation layer is not "selectively configurable between at least an extended size and a contracted size," as recited in claim 1. Moreover, claim 1 requires "an expandable collector member disposed on the retaining portion. . ." The expandable member (23d) of Bunce that the Examiner contends reads on the claimed "expandable collector member" is clearly not disposed on the separation layer (32) in Figure 4 or any where else within the disclosure of Bunce. See Bunce, Figure 4. Bunce, therefore, fails to teach each and every aspect of claim 1 and is, therefore, an improper reference under 35 U.S.C. 102(b). Accordingly, the Examiner's rejection of claim 1 under 35 U.S.C. 102(b) should be reconsidered and withdrawn.

Notwithstanding the fact that each of claims 2, 5-7, 10, 12-13 are dependent on claim 1, and as such are deemed to include each and every element of claim 1, Applicant submits that Bunce et al. also fail to teach those elements specifically recited in these dependent claims. Moreover, the Examiner has given no explanation as to what features of Bunce et al. are believed to read upon the additional limitations of these claims. Accordingly, these claims are also not anticipated by Bunce, and the rejection of these dependent claims should, therefore, be reconsidered and withdrawn.

Serial No. 09/997,023
Docket No.: 01:0793-034000

With respect to Claim 64, Applicant again reiterates that the Examiner has not indicated what features of Bunce are believed to read on the claimed method. Nevertheless, Applicant submits that Bunce does not disclose each and every limitation of claim 64. In particular, Bunce fails to disclose a method for collecting a sample adequate for assay comprising, *inter alia*, the steps of "providing a collector holder, the collector holder including a sample for indicating whether the sample collector has a sample sufficient for assay. . . and disposing the sample collector within the sample area such that the entirety of the sample collector is contained within the sample area." Even if the Examiner were to construe items (32), and (23), shown in Figure 4 of Bunce to read on the claimed "collector holder" and "sample collector," the disclosure of Bunce would be insufficient to anticipate claim, because item (32) is not a collector holder, but rather a "separation layer," as clearly described in the disclosure of Bunce. The disclosed separation layer (32) does not include a sample area. Accordingly, Bunce does not disclose the recited step of providing a collector holding including a sample area. Moreover, even if the Bunce did include a sample collector, item (23) is clearly not disposed in item (32). Thus, Bunce clearly fails to teach the step of disposing the sample collector within the sample area such that the entirety of the sample collector is contained within the sample area. For these reasons, the rejection of claim 64 should be reconsidered and withdrawn.

Notwithstanding the fact that each of claims 65-67 are dependent on claim 64, and as such are deemed to include each and every element of claim 64, Applicant submits that Bunce et al. also fail to teach those elements specifically recited in these dependent claims. Accordingly, these claims are also not anticipated by Bunce, and the rejection of these claims should also be withdrawn.

III. Claim Rejection Under 35 U.S.C. 102(b) in view of U.S. Patent No. 3,713,755 to Schmitz

Claims 1, 3, 7-8, 10, 12-13, 64-66 and 14-25 are rejected under 35 U.S.C. 102(b) as being anticipated by the disclosure of U.S. Patent No. 3,713,775 to Schmitz (hereinafter "Schmitz"). In particular, it is contended that Schmitz teaches in Figures 2-3 a pipette (51) having a first and second end. The interior of the pipette retains is said to retain a sample and plunger (54) has been read on the claimed "expandable collection member" having a first and second size. The pipette tip (55) has been read on the claimed "discharge member" and place the sample in curette (36) containing reagents (210).

Serial No. 09/997,023
Docket No.: 00793-034000

Applicant respectfully submits that Schmitz fails to disclose each and every limitation of the rejected claims, as required for under 35 U.S.C. 102(b). In particular, with respect to independent claim 1, Applicant notes that Schmitz does not teach or suggest a retaining portion coupled to the holding portion second end. Instead, the plunger which is said to read on the "expandable collection member" is merely inserted into the pipette (51), and not coupled thereto. Moreover, contrary to the Examiner's suggestion, plunger (54) is neither disposed on the pipette, which the Examiner contends reads on the "retaining portion," nor does plunger have a first collection size when the pipette retains a first collection size when the collector has a first amount of the sample and a second collection size when the collector member has a second amount of sample. . . " as recited in claim 1. Rather, it is clear from the disclosure of Schmitz that the plunger (54) rests within, and not on, pipette (51), and that the size of plunger (54) is fixed and does not change with the amount of sample in pipette (51). Schmitz therefore is an improper reference under 35 U.S.C. 102(b), and the rejection of claim 1, should therefore be withdrawn. Inasmuch as claims 3, 7-8, 10, and 12-13 are dependent on claim 1, the rejection of these claims should also be reconsidered and withdrawn.

Claim 3 is dependent on claim 1, and includes the further limitation that "wherein the retaining portion includes a discharge member spaced from the holding portion second end, the collector member being disposed between the discharge member and the holding portion second end, wherein when the retaining portion is moved from the extended size to the sample retaining size, a portion of sample in the retaining portion suitable for assay is discharged from the collector member." Applicant submits, however, that the plunger (54) of Schmitz, which as been read on the "expandable collector member" is not disposed between the pipette tip (54), which has been read on the "discharge member" and the second end of the pipette (51) interior which has been read on the "retaining portion." Rather, at least a portion of the plunger (54) necessarily sits outside of the pipette (51) in order for plunger (54) to be functional. Accordingly, because Schmitz fails to teach the recited "collector member being disposed between the discharge member and the holding portion second end," Schmitz fails to teach each and every limitation of claim 3. For this reason, and the reasons discussed above with respect to claim 1, the rejection of claim 3 should be reconsidered and withdrawn.

Claim 7 is dependent on claim 1, and includes the further limitation, "wherein the holding portion includes a housing defining an opening for slidably receiving the retaining portion so as to permit the retaining portion to be selectively movable between at least one of the extended size and the contracted size. Applicant submits that the Examiner's interpretation of Schmitz does not correlate with the limitation of claim 7. In particular, the

Serial No. 09/997,023
Docket No.: 00793-034000

Examiner has read the interior of pipette (51) to read on the recited "retaining portion." However, Applicant submits that the interior of pipette (51) does not define an opening, since the interior of pipette (51) is itself the opening. Moreover, the interior of pipette (51) does not slidably receive the interior of pipette (51). The Examiner's interpretation of Schmitz simply does not make sense as applied to the claimed invention. Since Schmitz fails to disclose "a holding portion which includes a housing defining an opening for slidably receiving the retaining portion, . . ." Schmitz does not anticipate the invention of claim 7. Accordingly, the rejection of claim 7 should be reconsidered and withdrawn.

Claim 8 is dependent on claim 1 and includes the limitation, "the collector member being disposed between the discharge member and the holding portion second end." For those reasons discussed above with respect to claim 3, Schmitz does not anticipate the invention of claim 8. The rejection of claim 8 should, therefore, be reconsidered and withdrawn.

Independent claim 46 is directed to a sample collection device including the limitation of "a retaining portion coupled to the holding portion second end and selectively configurable between at least an extended size and a sample retaining size. . ." As noted above, the Examiner has read the pipette (51) on the "holding portion" and the interior of pipette (51) as being the "retaining portion." Under the Examiner's interpretation, it is clear that the interior of pipette (51) is not coupled to the second end of the pipette (51). Therefore, Schmitz fails to teach the limitation of claim 1 requiring "a retaining portion coupled to the holding portion second end. . ." Claim 46 further recites "a blocking portion disposed on the retaining portion, the blocking portion being spaced from the holding portion second end when the retaining portion is configured in the extended size and the blocking portion engaged with the holding portion second end when the retaining portion is configured in the sample size." Schmitz, however, does not disclose a blocking portion. Claim 46 also recites an "expandable collection member disposed on the retaining portion and having a first collection size when the collector member has a first amount of sample and a second collection size when the collector member has a second amount of sample. Again, the Examiner has read the plunger (54) of Schmitz on the "expandable collection member." As discussed above, plunger (54) is not disposed on the interior of pipette (54), which the Examiner has read on the "retaining portion"; rather plunger (54) is disposed within the interior of pipette (54). Further, the plunger (54) of Schmitz is clearly of a fixed length, and does not have a first collection size and a second collection size, as required by claim 46. Schmitz, therefore, fails to teach each and every limitation of claim 46 as required under 35 U.S.C. 102(b).

Serial No. 09/997,023
Docket No.: C-0793-034000

Accordingly the rejection of claim 46 should be reconsidered and withdrawn. Inasmuch as claim 47-52 are dependent on claim 46, and deemed to include each and every limitation thereof, the rejection of claims 47-52 should also be reconsidered and withdrawn.

For substantially the same reasons discussed above with respect to claim 64, Applicant submits that Schmitz also fails to disclose the method of claim 64. Claim 64, for example, is directed to a method for collecting a sample adequate for assay, comprising the steps of "providing a sample collector for collecting a sample. . ." "providing a collector holder. . ." "disposing the sample collector within the sample area such that the entirety of the sample collector is contained within the sample area," "collecting a sample on the sample collector," and "comparing the size of the sample collector to the sample adequacy size. . ." Unfortunately, the Examiner has failed to indicate what feature of Schmitz are believed to read on the limitation of claim 46. Even if the Examiner were to determine that the plunger (54) of Schmitz reads on the "sample collector" and the pipette (51) of Schmitz on the recited "collector holder," it is obvious as the teachings of Schmitz would be deficient to enable one to practice the method of the claimed invention. For example, claim 46 requires a "sample collector having a second size when a sufficient sample for assay is contained in the sample collector and a first size when an insufficient sample is contained in the sample collector." It is obvious, however, that the plunger (54) of Schmitz is of fixed size and does not have a first size and second size as claim 46 recites. Moreover, a sample is not "contained" in plunger (54). Claim 46 further requires the step of "collecting a sample on the sample collector." In the teachings of Schmitz, however, a sample is not collected on plunger (54)." Clearly, Schmitz fails to teach each and every aspect of claim 64 as required by 35 U.S.C. 102(b). Accordingly, the Examiner's rejection of claim 64 also be reconsidered and withdrawn. Inasmuch as claim 65-66 are dependent on claim 64, the rejection of claims of claims 65-66 should also be reconsidered and withdrawn.

IV. Claim Rejection Under 35 U.S.C. 102(b) in view of U.S. Patent No. 4,750,373 to Shapiro; U.S. Patent No. 4,036,064 to Hydo; or U.S. Patent No. 5,364,596 to Magnussen et al.

Claims 1, 3, 7-8, 10, 12-13, 46-51, and 64-66 are also rejected under 35 U.S.C. 102(b) as being anticipated by the disclosure of U.S. Patent No. 4,750,373 (hereinafter "Shapiro"), U.S. Patent No. 4,036,064 to Hydo (hereinafter "Hydo") or U.S. Patent No. 5,364,596 to Magnussen et al. (hereinafter "Magnussen et al."). In particular, it is contended in the Office Action that these references teach sample collection means having a plunger with multiple

Serial No. 09/997,023
Docket No.: 010793-034000

positions and stops, which have been read on the claimed first and second holding positions. Unfortunately, it is difficult for Applicant to respond to the Examiner's rejection in view of these references, since the Examiner has provided no further indication as to what, if any, features of these references are considered to read on those other elements of the claimed invention. Moreover, it is not clear as to what first and second "holding position" the Examiner refers. Each of Shapiro, Hydo, and Magnussen et al. are directed to pipettes with designs significantly different that defined by the claimed invention. With respect to independent claim 1, particularly noteworthy is that while these references teach a pipette body, the references fail to teach a separate holding portion. Or, on the other hand, if the pipette body is construed to read on the holding portion, the references fail to teach a separate retaining portion. Moreover, neither of these references teach the limitation of: "expandable collection member expandable collector member disposed on the retaining portion and having a first collection size when the collector member has a first amount of sample and a second collector size when the collector member has a second amount of sample, the first collection size being less than the second collection size." Any argument that the plunger portion of the pipettes of Hydo, Shapiro and Magnussen et al reads on the recited "expandable collector member" ultimately fails, as the plunger portion of these pipettes is clearly stationary and non-expandable. Likewise, the plunger portion of the pipettes taught by these references cannot have "a first collection size when the collector member has a first amount of sample, and a second collection size when the collector member has a second amount of sample. . ." as required by independent claim 1. Therefore, since Hydo, Shapiro and Magnussen et al. do not teach or suggest each and every element of the claimed invention, the rejection of claim 1 should be reconsidered and withdrawn.

The rejection of claims 3, 7-10, and 12-13 should likewise be withdrawn since these claims are deemed to include each and every element of claim 1 by virtue of being dependent thereon. However, Applicant also submits that the Hydo, Shapiro, and Magnussen et al. also do not teach each and every element of these dependent claims, and the Examiner has provided no indication otherwise.

Claim 46 likewise requires a holding portion, a retaining portion, a blocking portion, and an expandable collector member. For substantially the same reasons as discussed above, the teachings of Hydo, Shapiro, and Magnussen et al. are clearly do not teach structures corresponding to each and every one of these elements, and the Examiner has not providing a showing otherwise. Accordingly, the rejection of these claims should be reconsidered and withdrawn.

Serial No. 09/997,023
Docket No.: 00793-034000

The rejection of claims 47-51 should likewise be withdrawn since these claims are also deemed to include each and every element of claim 46 by virtue of being dependent thereon. However, Applicant also submits that the Hydo, Shaprio, and Magnussen et al. also do not teach each and every element of these dependent claims. Again, the Examiner has provided no indication otherwise and has not provided Applicant with any indication of what structures of Hydo, Shaprio, and Magnussen et al. are deemed to read on the elements recited in these claims. For these reasons too, Applicant submits that the rejection of claims 47-51 should be withdrawn.

Finally, with respect to rejection of claim 64-66, Applicant, again, submits that these references fail teach or suggest each and every claimed element as required under 35 U.S.C. 102(b). Independent claim 64, for example, requires the step of "providing a sample collector for collecting sample, the sample collector having a second size when a sufficient sample for assay is contained in the sample collector and a first size when an insufficient sample is contained in the sample collector." The Examiner has read the pipettes taught by Hydo, Shapiro, and Magnussen et al. on the claimed sample collector. It is clear, however, the size of the pipettes of these references does not change in size depending on the amount of sample contained therein. The Examiner's interpretation of the pipettes taught by these references, therefore, does not correlate, or read on, the invention of claim 64.

Claim 64 further recites the steps of "providing a collector holder, the collector holder including a sample area for indicating whether a sample collector has collected a sample sufficient for assay; disposing the sample collector within the sample area such that the entirety of the sample collector is contained within the sample area; collecting a sample on the sample area; and comparing the size of the sample collector to the sample adequacy size and if the sample adequacy size is approximately equal to the second size then an adequate sample is collected for assay." The pipettes taught by Hydo, Shapiro, and Magnussen et al., however, do not include a collector holder, and especially do not include a collector hold including a sample area, for example, as claimed. For these reasons, the rejection of independent claim 64 should be reconsidered and withdrawn.

The rejection of claims 65-66 should likewise be withdrawn since these claims are also deemed to include each and every element of claim 64 by virtue of being dependent thereon. However, Applicant also submits that the Hydo, Shaprio, and Magnussen et al. also do not teach each and every element of these dependent claims. Again, the Examiner has provided no indication otherwise and has not provided Applicant with any indication of what steps of Hydo, Shaprio, and Magnussen et al. are deemed to read on the elements recited in

Serial No. 09/997,023
Docket No.: 00793-034000

these claims. For these reasons too, Applicant submits that the rejection of claims 47-51 should be withdrawn.

V. Conclusion

In view of the foregoing, Applicant submits all of the cited references, whether taken alone or combined, fail to teach, suggest, or render obvious each and every aspect of the claimed invention. Accordingly, it is respectfully submitted that claims 1-3, 5-8, 10, 12-25, 46-52, and 64-67 should be reconsidered and withdrawn.

Having responded to each and every rejection set forth in the Office Action, it is respectfully submitted that the application should now be in condition for allowance. Accordingly, an early Notice of Allowance is courteously requested. Should there be any outstanding issues to be resolved, the Examiner is invited to contact the undersigned by telephone to expedite the prosecution of the case.

Respectfully submitted,

NIXON PEABODY LLP


Jeffrey A. Linderman

Registration No. 34,658

NIXON PEABODY LLP

401 9th Street, N.W.

Suite 900

Washington, D.C. 20004-2128

(202) 585-8000

(202) 585-8080 FAX